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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,174	02/07/2002	John C. Reed	087102 0272558	2991

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Pillsbury Winthrop LLP
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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,174

Applicant(s)

REED ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-141 is/are pending in the application.
- 4a) Of the above claim(s) 24, 25 and 29-141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the communication filed on 10/12/04. Claims 1-141 are currently pending in the application and are addressed herein.

Election/Restrictions

Applicant's election of Group I (claims 1-28, 42-45, 76 and 77 wherein the nucleic acid encodes a polypeptide) and election of the species "adenovirus" in the reply filed on 10/12/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 29-41, 46-75 and 78-141 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/12/04.

Claims 1-28, 42-45, 76 and 77 and the species "adenovirus" are examined herein.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 3/8/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner (see attached form PTO-1449).

Claim Rejections - 35 USC § 112, 2nd paragraph

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23, 26-28, 43-45, 76 and 77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "at least about" in claims 1-4, 17 43-45, 76 is a relative term which renders the claim indefinite. The term "at least about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the exact amount of identity between the isolated or recombinant nucleic acid and SEQ ID NO: 1 is indefinite. Claims 11-15, 18-23, 26-28, 77 are rejected because they are dependent claims that, by definition, encompass all of the limitations of the independent claim.

The term "less than about" in claims 5-9 is a relative term which renders the claim indefinite. The term "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the exact size limitation of the sequence is indefinite.

The term "less than about" in claim 10 is a relative term which renders the claim indefinite. The term "less than about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the exact size limitations of the sequence are indefinite.

The term "a length of about" in claim 16 is a relative term which renders the claim indefinite. The term "of about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, the exact length of the sequence is indefinite.

Claim 10 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 10 recited the phrase, "wherein the sequence is between about 2.5kB and 1kB, 1kB and 0.5kB, 0.5kB and 0.25kB and 0.1kB and 15 base pairs." (Emphasis added). Here the claim appears to encompass 4 different size ranges that the sequence can be; however, the size ranges are not claimed in the alternative. Therefore the claim is indefinite because it is unclear how a sequence can be "between about 2.5kB and 1kB, 1kB and 0.5kB, 0.5kB and 0.25kB and 0.1kB and 15 base pairs." It is noted that amending the claim by changing the claims such that the ranges were claimed in the alternative (i.e., the indicated "and" is changed to "or") would obviate this rejection.

Claim 13 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 13 recites the phrase, "wherein the sequence comprises a plurality of sequences attached to a substrate". This phrase renders the claim indefinite because it is unclear how the sequence (i.e., one sequence) can comprise a plurality of sequences (i.e., multiple sequences). It is noted that amending the claim such that "a plurality of sequences" is

changed to “a plurality of nucleotides” or “a plurality of nucleic acids” would obviate this rejection.

Claims 1-16 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1 and 15 recite the limitation “wherein the sequence is distinct from **EST Accession no. AA098865.**” (Emphasis added). It is noted that the specification does not disclose the sequence of EST Accession no. AA098865. Furthermore, EST Accession numbers are not static throughout time and may be amended or updated after the initial submission. Therefore, the phrase “EST Accession no. AA098865” renders the claims indefinite because the sequence of EST Accession no. AA098865 is indefinite in view of the instant disclosure. Claims 2-14, 16 and 26-28 are dependent claims that are rejected for the same reason.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-23, 26-28, 42-45, 76 and 77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Written Description Guidelines for examination of patent applications indicates, “the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus.” (See MPEP 2100-164)

The instant claims are drawn to an isolated/recombinant nucleic acid that has a specified level of identity to SEQ ID NO:1 (i.e., 70%, 80%, 90%, 95% identity) wherein the nucleic acid is distinct from EST Accession No. AA098865. As such, the claims are drawn to a genus of nucleic acid sequences which are different from the sequences explicitly disclosed in the specification. The genus of claimed nucleic acid sequences encompass an indefinite number of distinct nucleic acid sequences (possibly thousands) considering every possible nucleic acid sequence that is encompassed by the claims and includes sequences which have yet to be identified. It is noted that for claims 1-10, 12-23, 26-28, 76 and 77, the claims do not specifically indicate any particular function for the nucleic acids encompassed by the claims. As such claims 1-10, 12-23, 26-28, 76 and 77 encompass nucleic acid molecules that could have completely unrelated functions, yet still meet the sequence identity limitations of the claims. Furthermore, claims 42-45 do specifically indicate that the nucleic acids encompassed by the claims must be able to “modulate apoptosis”. Regarding “modulating apoptosis” it is noted that the claims encompass molecules that can increase or decrease apoptosis. As such the claims encompass nucleic acids that can have completely opposite functions (increasing apoptosis and

decreasing apoptosis), yet meet the sequence identity limitations set forth in the claims. Furthermore, regarding “modulating apoptosis” the specification does not disclose any structure-function relationship for the claimed genus of sequences that would identify the elements of the sequences that are critical for their function. As such, the specification has not disclosed which sequences that meet the limitations set forth in the claims (other than SEQ ID NO:1 itself) would have the desired function (i.e., modulating apoptosis) and which sequences encompassed by the claims would not have the desired function. Therefore, the specification has failed to adequately describe the genus of sequences encompassed by the claims.

It is noted that amending the claims to the nucleic acid that is SEQ ID NO:1 would obviate this rejection.

Additionally, claims 1-10, 12-23, 26-28, 42-45, 76 and 77 are also rejected under 35 U.S.C. 112, first paragraph (in view of the written description rejection above), because the specification, while being enabling for the indicated claims wherein the claims are limited to SEQ ID NO:1, does not reasonably provide enablement for the full scope encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As mentioned above, the claims encompass sequence for which there is insufficient written description provided in the specification. Without a clear disclosure of the sequences encompassed by the claims one of skill in the art would not know how to make or use the claimed invention without performing an undue amount of additional experimentation to first identify the sequences having the desired function.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-23, 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/00506 (KATO et al.).

KATO teaches an isolated nucleic acid sequence (see SEQ ID NO:23 of KATO) that is 91.6% identical to SEQ ID NO:1 (see the attached sequence alignment). SEQ ID NO:23 of KATO is a sequence that is 1168 nucleotides in length (e.g., see Sequence Listing page 20/45). Furthermore, KATO teaches cDNA fragments (more than 10 bp) including antisense nucleotide sequences that can be used as probes (e.g., see p. 11, lines 8-15) that hybridize to related DNA sequences (e.g., see p. 12, lines 5-8). It is noted that the specification does not disclose a limiting definition of “stringent hybridization conditions”. In view of the open definition of “stringent hybridization conditions”, the probes described by KATO would inherently hybridize to SEQ ID NO:1 under such conditions. Furthermore, the probes described by KATO (e.g., p.11-12) would also encompass probes that are subsequences of SEWQ ID NO:1 that are at least 15bp long. KATO also teaches that the probes can be to a “gene chip” or other support (e.g., see p. 12 lines 10-15). It is noted that the specification does not appear to explicitly define the limitation “substrate”. As such, the attachment of the nucleic acid to a “gene chip” (as taught by KATO, e.g. page 12) would constitute attaching the sequence to a substrate. Furthermore, hybridizing a sequence to the nucleic acid sequence (e.g., such as a examining expression patterns—see p. 12)

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would constitute attaching a plurality of sequences (i.e., a plurality of nucleotides) to a substrate at defined positions. KATO also teaches that the nucleic acid sequence that meets the instant limitations can be comprised in an expression vector such that the vector operably encodes and expresses the polypeptide encoded therein (e.g., see p. 7 lines 2-23). KATO teaches that the expression construct can have a promoter, such as the cytomeglovirus (CMV) promoter (a constitutive promoter) wherein the construct can express the encoded polypeptide in a cell, including a mammalian cell. KATO also teaches the construct can be comprised in a viral vector such as an EBV vector (it is noted that EBV is a herpes virus) (e.g., see p. 7). Furthermore, KATO teaches that the vector can be transformed into cell wherein the cell is a bacterial cell or a eukaryotic cell, including a mammalian cell (e.g., see p. 7, lines 2-23).

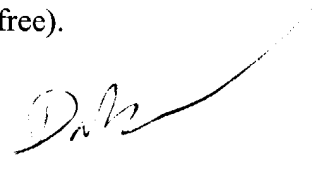
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Jon Eric Angell", with a long horizontal flourish extending to the right.

Jon Eric Angell, Ph.D.
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